

**Eli Lilly and Company**  
**Material Safety Data Sheet**MSDS Index**Vancomycin Hydrochloride for Injection**

Effective Date: 21-May-2004

**Section 1 - Chemical Product and Company****Manufacturer:**  
Eli Lilly and Company  
Lilly Corporate Center  
Indianapolis, IN 46285**Emergency Phone:**  
1-317-276-2000  
**CHEMTREC:**  
1-800-424-9300 (North America)  
1-703-527-3887 (International)**Common Name:** Vancomycin Hydrochloride for Injection**Chemical Name:** Vancomycin, hydrochloride**Synonym(s):** Vancomycin; 020460 Formulation; 028811 Hydrochloride Formulation**Tradename(s):** Vancocin; Diatracin; Vancocina CP; Voncon; Vanocin CP; Vancocine; Vancocina; Enterocaps; Fibrantil**Lilly Item Code(s):** AM0657; MS8113; MS8456; UC5387; UC5388; UC8967; UC8969; UC9509; VF0153; VF0154; VF0157; VF0158; VF0168; VF0169; VF0170; VF0180; VF0189; VF0190; VF0191; VF0193; VF0207; VF0232; VF0233; VF0379; VF0380; VF0381; VL0657; VL7229; VL7297; VL7298; VL7321; VL7355; VL7357; VL7358; VL7367; VL7368; VL7376; VL7377; VL7467; VL7629; VL7630

See attached glossary for abbreviations.

**Section 2 - Composition / Information on Ingredients**

<u>Ingredient</u>	<u>CAS</u>	<u>Concentration %</u>
Vancomycin Hydrochloride	1404-93-9	96
Ethyl Alcohol	64-17-5	3

**Exposure Guidelines:**Vancomycin hydrochloride - LEG <100 micrograms/m<sup>3</sup> TWA for 12 hours.Ethyl alcohol - PEL and TLV 1000 ppm (1900 mg/m<sup>3</sup>) TWA.UK - Exposure Standard 1000 ppm (1920 mg/m<sup>3</sup>) TWA.Ireland - Occupational Exposure Limit 1000 ppm (1900 mg/m<sup>3</sup>) TWA.France - Occupational Exposure Limit 1000 ppm (1900 mg/m<sup>3</sup>) (VME) TWA, 5000 ppm (9500 mg/m<sup>3</sup>) (VLE) STEL.Germany - TRGS 900 Limit Value 500 ppm (960 mg/m<sup>3</sup>), 15-minute limit not to exceed 4 times MAK.

Exhibit D

## Section 3 - Hazards Identification

**Appearance:** Off-white lyophilized plug

**Physical State:** Solid

**Odor:** Odorless

### Emergency Overview



Special  
A = Allergen

**Emergency Overview Effective Date:** 13-Aug-1999

**Lilly Laboratory Labeling Codes:**

**Health 2**

**Fire 1**

**Reactivity 0**

**Special A**

**Primary Physical and Health Hazards:** Irritant (eyes). Allergen. Nervous System Effects.

**Caution Statement:** Vancomycin Hydrochloride for Injection contains ethyl alcohol, may be irritating to the eyes and causes allergic reactions. Effects of exposure may include dizziness, nausea, and drowsiness.

**Routes of Entry:** Inhalation and skin contact.

**Effects of Overexposure:** None reported; however, the components may produce signs and symptoms as indicated.

Vancomycin hydrochloride - Allergic reactions to vancomycin have been reported including nasal congestion, itching and runny nose, watery eyes, and mild breathing difficulties or skin irritation with a rash and itching with or without hives. May be irritating to the eyes. The following events have been reported with therapeutic use of vancomycin: flushing (redness of the face), low blood pressure, nausea, dermatitis, rash, hearing loss, kidney effects, blood effects (IV only), and anaphylactic reactions.

Ethyl alcohol - May include irritation of the eyes, skin, and respiratory tract, drowsiness, nausea, muscle incoordination, visual impairment, slowed reaction time, sensory loss, slurring of speech, stupor, and possible coma and death.

**Medical Conditions Aggravated by Exposure:** None known; however, the components may aggravate preexisting conditions as indicated.

Vancomycin hydrochloride - Hypersensitivity to vancomycin.

Ethyl alcohol - Ingestion of large volumes may aggravate liver disorders, hypersensitivity to alcohol, and gastrointestinal abnormalities (peptic ulcers, gastritis).

#### **Carcinogenicity:**

Vancomycin hydrochloride - Not listed by IARC, NTP, ACGIH, or OSHA.

Ethyl alcohol - ACGIH A4 - (not classifiable as a human carcinogen). Not listed by NTP or

OSHA. Alcohol drinking is listed as IARC Group 1.

## Section 4 - First Aid Measures

**Eyes:** Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. See an ophthalmologist (eye doctor) or physician immediately.

**Skin:** Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with plenty of soap and water. Get medical attention if irritation develops.

**Inhalation:** Move individual to fresh air. Get medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance (mouth-to-mouth) and call a physician immediately.

**Ingestion:** Do not induce vomiting. Call a physician or poison control center. If available, administer activated charcoal (6-8 heaping teaspoons) with two to three glasses of water. Do not give anything by mouth to an unconscious person. Immediately transport to a medical care facility and see a physician.

### Notes to Physician:

Vancomycin - Supportive care is advised, with maintenance of glomerular filtration. Vancomycin is poorly removed from the blood by dialysis. Hemofiltration and hemoperfusion with polysulfone resin have been reported to result in increased vancomycin clearance.

## Section 5 - Fire Fighting Measures

**Flash Point:** No applicable information found

**UEL:** No applicable information found

**LEL:** No applicable information found

**Extinguishing Media:** Use water, carbon dioxide, dry chemical, foam, or Halon.

**Unusual Fire and Explosion Hazards:** As a finely divided material, may form dust mixtures in air which could explode if subjected to an ignition source.

**Hazardous Combustion Products:** May emit toxic fumes when exposed to heat or fire.

## Section 6 - Accidental Release Measures

**Spills:** Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions). Vacuum material with appropriate dust collection filter in place. Be aware of potential for dust explosion when using electrical equipment. If vacuum is not available, lightly mist material and remove by sweeping or wet wiping.

## Section 7 - Handling and Storage

**Storage Conditions:** Refrigerator: 2 to 8 C (36 to 46 F).

## Section 8 - Exposure Controls / Personal Protection

See Section 2 for Exposure Guideline information. Under normal use and handling conditions, no protective equipment is required. The following is recommended for a production setting:

**Respiratory Protection:** Use an approved respirator.

**Eye Protection:** Chemical goggles and/or face shield.

**Ventilation:** Laboratory fume hood or local exhaust ventilation.

**Other Protective Equipment:** Chemical-resistant gloves and body covering to minimize skin contact. If handled in a ventilated enclosure, as in a laboratory setting, respirator and goggles or face shield may not be required. Safety glasses are always required.

**Additional Exposure Precautions:** In production settings, airline-supplied, hood-type respirators are preferred. Shower and change clothing if skin contact occurs.

## Section 9 - Physical and Chemical Properties

**Boiling Point:** Not applicable

**Melting Point:** Decomposes when heated

**Specific Gravity:** Not applicable

**pH:** 2.5 to 4.5 (5% aqueous)

**Evaporation Rate:** No applicable information found

**Water Solubility:** Soluble

**Vapor Density:** No applicable information found

**Vapor Pressure:** No applicable information found

## Section 10 - Stability and Reactivity

**Stability:** Stable at normal temperatures and pressures.

**Incompatibility:** May react with strong oxidizing agents (e.g., peroxides, permanganates, nitric acid, etc.).

**Hazardous Decomposition:** May emit toxic fumes when heated to decomposition.

**Hazardous Polymerization:** Will not occur.

## Section 11 - Toxicological Information

### Acute Exposure

No data available for mixture or formulation. Data for ingredient(s) or related material(s) are presented.

**Oral:**

Vancomycin hydrochloride - Rat, 5000 mg/kg, no deaths, leg weakness, diarrhea.

Ethyl alcohol - Rat, median lethal dose 7060 mg/kg.

**Skin:**

Vancomycin hydrochloride - Rabbit, 500 mg/kg, no deaths or toxicity.

Ethyl alcohol - Rabbit, median lethal dose greater than 20 g/kg.

**Inhalation:**

Vancomycin hydrochloride - Rat, 3080 mg/m<sup>3</sup> for 1 hour, no deaths, increased activity.

Ethyl alcohol - Rat, median lethal concentration 20,000 ppm for 10 hours (approximately 200,000 ppm for 1 hour).

**Intravenous:**

Vancomycin hydrochloride - Rat, median lethal dose between 251 and 312 mg/kg, convulsions, labored breathing, reduced activity.

Dog, median lethal dose 292 mg/kg, increased blood urea nitrogen, renal failure.

**Skin Contact:**

Vancomycin hydrochloride - Rabbit, nonirritant

Ethyl alcohol - Rabbit, irritant

**Eye Contact:**

Vancomycin hydrochloride - Rabbit, irritant

Ethyl alcohol - Rabbit, irritant

## **Chronic Exposure**

No data available for mixture or formulation. Data for ingredient(s) or related material(s) are presented.

**Target Organ Effects:**

Vancomycin hydrochloride - Nervous system effects (weakness, incoordination, vomiting, shaking), heart effects (decreased blood pressure, change in heart rate/rhythm), blood effects (increased reticulocyte count, decreased lymphocyte count, changes in blood chemistry), kidney effects (kidney tissue changes), digestive effects (intestinal tissue changes).

Ethyl alcohol - Nervous system effects (depression), liver and kidney effects (tissue changes).

**Other Effects:**

Vancomycin hydrochloride - Decreased body weight, excessive salivation.

**Reproduction:**

Vancomycin hydrochloride - Reduced fetal body weight at doses toxic to the mother.

Ethyl alcohol - Decreased fertility, fetal growth retardation, increased behavioral abnormalities in offspring, and decreased offspring survival at doses toxic to the mother.

**Sensitization:** No applicable information found.

**Mutagenicity:**

Vancomycin hydrochloride - Not mutagenic in bacterial or mammalian cells.

Ethyl alcohol - Not mutagenic in bacterial or mammalian cells.

## Section 12 - Ecological Information

No environmental data for the mixture or formulation. The environmental information for ingredient(s) or related material(s) are presented.

### Ecotoxicity Data:

Ethyl alcohol

Rainbow trout 96-hour median lethal concentration: 13 g/L

Fathead minnow 96-hour median lethal concentration: 13.5 g/L

Daphnia magna 48-hour median lethal concentration: 9.3 g/L

Blue-green algae (*A. aeruginosa*) 8-day median effective concentration: 1450 mg/L

Microorganisms:

Green algae (*C. pyrenoidosa*): MIC 1.18%

### Environmental Fate:

Ethyl alcohol

Log Kow: -0.31

Atmospheric half-life (days): 4 to 5.9

5-Day biological oxygen demand: 37 to 86%

### Environmental Summary:

Ethyl alcohol - Practically non-toxic to aquatic organisms. Material can be considered not to bioaccumulate and will have little adsorption to the soil. Ethanol will photodegrade and biodegrade when released to the environment and can not be considered to be persistent in the environment.

## Section 13 - Disposal Considerations

**Waste Disposal:** Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

## Section 14 - Transport Information

### Regulatory Organizations:

**DOT:** Not Regulated

**ICAO/IATA:** Not Regulated

**IMO:** Not Regulated

## Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Eli Lilly and Company usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

### **U.S. Regulations**

Vancomycin hydrochloride

TSCA - No

CERCLA - Not on this list

SARA 302 - Not on this list

SARA 313 - Not on this list

OSHA Substance Specific - No

Ethyl alcohol

TSCA - Yes

CERCLA - Not on this list

SARA 302 - Not on this list

SARA 313 - Not on this list

OSHA Substance Specific - No

### **EU Regulations**

#### **EC Classification**

Contains vancomycin hydrochloride (C = 96%).

Xn (Harmful)

Xi (Irritant)

#### **Risk Phrases**

R 36 - Irritating to eyes.

R 42/43 - May cause sensitization by inhalation and skin contact.

#### **Safety Phrases**

S 25 - Avoid contact with eyes.

S 26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S 36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.

## **Section 16 - Other Information**

### **MSDS Sections Revised: Sections 3 and 4.**

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Eli Lilly and Company

Hazard Communication

317-433-7171

For additional copies contact:  
Eli Lilly and Company  
1-800-LILLY-Rx (1-800-545-5979)

**GLOSSARY:**

ACGIH = American Conference of Governmental Industrial Hygienists  
AIHA = American Industrial Hygiene Association  
BEI = Biological Exposure Index  
CAS Number = Chemical Abstract Service Registry Number  
CERCLA = Comprehensive Environmental Response Compensation and Liability Act (of 1980)  
CHAN = Chemical Hazard Alert Notice  
CHEMTREC = Chemical Transportation Emergency Center  
DOT = Department of Transportation  
EC = European Community  
EINECS = European Inventory of Existing Chemical Substances  
ELINCS = European List of New Chemical Substances  
EPA = Environmental Protection Agency  
HEPA = High Efficiency Particulate Air (Filter)  
IARC = International Agency for Research on Cancer  
ICAO/IATA = International Civil Aviation Organization/International Air Transport Association  
IEG = Lilly Interim Exposure Guideline  
IMO = International Maritime Organization  
Kow = Octanol/Water Partition Coefficient  
LEG = Lilly Exposure Guideline  
LEL = Lower Explosive Limit  
MSDS = Material Safety Data Sheet  
MSHA = Mine Safety and Health Administration  
NA = Not Applicable, except in Section 14 where NA = North America  
NADA = New Animal Drug Application  
NAIF = No Applicable Information Found  
NCI = National Cancer Institute  
NIOSH = National Institute for Occupational Safety and Health  
NOS = Not Otherwise Specified  
NTP = National Toxicology Program  
OSHA = Occupational Safety and Health Administration  
PEL = Permissible Exposure Limit (OSHA)  
RCRA = Resource Conservation and Recovery Act  
RQ = Reportable Quantity  
RTECS = Registry of Toxic Effects of Chemical Substances  
SARA = Superfund Amendments and Reauthorization Act  
STEG = Lilly Short Term Exposure Guideline  
STEL = Short Term Exposure Limit  
TLV = Threshold Limit Value (ACGIH)  
TPQ = Threshold Planning Quantity  
TSCA = Toxic Substances Control Act  
TWA = Time Weighted Average/8 Hours Unless Otherwise Noted  
UEL = Upper Explosive Limit  
UN = United Nations  
WEEL = Workplace Environmental Exposure Level (AIHA)